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EXAMINER	
KASZTEJNA, MATTHEW JOHN	
ART UNIT	PAPER NUMBER
3739	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,485	SAADAT ET AL.	
	Examiner	Art Unit	
	MATTHEW J. KASZTEJNA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-71,73,74,76-80,82-84,92 and 94-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-71,73,74,76-80,82-84,92 and 94-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on November 30, 2009, amended claims 67, 92 and 95 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 67-71, 73-74, 76-80, 82-83, and 95-96 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,251,611 to Zehel et al.

In regards to claims 67, Zehel et al. disclose an endoluminal apparatus 1 comprising: an elongated main body 11 having a proximal end, a distal end, a longitudinal axis and at least one lumen 29 extending through the main body the main body comprising a single tube having at least a first section near the proximal end and a second section 12 near the distal end (see Fig. 1), and with the first section comprising a plurality of nested links 19 with substantially all adjacent links having mating surfaces that are in contact with but that are not connected to each other (see Fig. 3 and Col. 6, Lines 35-38) and having a plurality of first pullwire lumens 21, a plurality of first pullwires 20 routed through substantially each of the first pullwire lumens, with each of the first pullwires being fixed to the elongated main body at a location at or near a distal end of

the first section and at substantially a common point along the longitudinal axis of the main body, the first pullwires being substantially symmetrically spaced around the periphery of the nested links of the first section (see Figs. 2 and 4 and Col. 6, Line 60 – Col. 7, Line 15), a tensioning mechanism 16 operatively coupled to each of the first pullwires and adapted to impart tension force that is substantially evenly distributed to each of the first pullwires (see Col. 7, Lines 40-50), wherein the first section may be selectively switched between a substantially flexible condition and a substantially rigid condition (see Col. 7, Lines 1-14) wherein the second section is steerable relative to the first section (see Col. 5, Lines 1-27); and a scope being movable through the lumen relative to the elongated main body (see Col. 6, Lines 14-16 and Col. 8, Lines 40-42).

In regards to claim 68, Zehel et al. disclose an endoluminal apparatus, wherein the main body includes a torque transmitting feature which provides torque transmission between the proximal and distal ends while the main body is unlocked, to cause the main body to rotate substantially about its central axis (see Col. 5, Line 65 – Col. 6, Liner 10).

In regards to claim 69, Zehel et al. disclose an endoluminal apparatus, comprises an atraumatic tip 40 having at least one opening corresponding to the at least one lumen (see Figs. 7-8 and Col. 9, Lines 20-40).

In regards to claim 70, Zehel et al. disclose an endoluminal apparatus, wherein the second section 12 may be switched between a flexible state and a substantially rigid state independently of the first section (see Col. 5, Lines 48-65). It is noted, that the flexible device of the present invention, particularly the distal end thereof, may be

optionally fitted with a wide variety of instruments for conducting a wide variety of exploratory, surgical or other procedures. For example, the device may be fitted with retractors to assist in retracting tissue away from the point of interest, ultrasonic devices, which for example, may be used in exploratory procedures, irrigation/suction devices for use in surgical procedures, tissue clipping devices, voice activated directional equipment, lock-on devices and the like. The procedures which may be conducted at the target point of the subject, once reached by the distal end of the flexible device, are likewise varied, and include, without limitation, visual inspection, polyp removal, biopsy, general surgery, photography, angioplasty, laser surgery and the like. Thus, as broadly as claimed, the distal end may be operated independently of the first section, and switched between a "flexible state" and a "rigid state".

In regards to claim 71, Zehel et al. disclose an endoluminal apparatus, with substantially each link in the first section configured to allow partial rotation relative to adjacent links and with the links arranged so that the first section can bend in at least two dimensions (see Figs. 5-6 and Col. 7, Line 63 – Col. 8, Line 10).

In regards to claims 73-74, Zehel et al. disclose an endoluminal apparatus, wherein the second section is steerable in up to three dimensions relative to the first section (see Col. 5, Lines 1-15).

In regards to claim 76, Zehel et al. disclose an endoluminal apparatus, further comprising at least two liners 10, 40 extending along a length of the elongated main body (see Figs. 7-8).

In regards to claim 77, Zehel et al. disclose an endoluminal apparatus, wherein at least one liner can transmit torque (see Col. 4, Lines 49-67).

In regards to claims 78-79, Zehel et al. disclose an endoluminal apparatus, further comprising a liner creating a lumen in the main body (see Figs. 8-9 and Col. 8, Lines 40-42). It is well known within the art to provide a hydrophilic coating on coaxial liners (see Col. 10, Lines 56-60).

In regards to claim 80, Zehel et al. disclose an endoluminal apparatus, wherein the scope comprises an endoscope extendable through the main body, with the scope having a steerable tip (see Col. 6, Lines 14-16 and Col. 8, Lines 40-42).

In regards to claim 82, Zehel et al. disclose an endoluminal apparatus, further comprising an insufflation lumen within the main body (see Col. 5, Lines 55-57).

In regards to claim 83, Zehel et al. disclose an endoluminal apparatus, wherein a first end of the endoscope is *positionable* in an off-axis position relative to the elongated main body such that a region of interest spaced apart from the elongated main body may be viewed at an angle via the endoscope (see Col. 6, Lines 11-19).

In regards to claim 95, Zehel et al. disclose an endoluminal apparatus, wherein the member positioned at a distal end of the first section is one of the plurality of nested link (see Fig. 2 and Col. 6, Lines 60-67).

In regards to claim 96, Zehel et al. disclose an endoluminal apparatus, wherein the tensioning mechanism comprises a pulley and wherein at least one of the first pullwires is routed though the pulley (see Col. 7, Lines 40-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,251,611 to Zehel et al. in view of U.S. Patent No. 3,897,775 to Furihata.

In regards to claim 84, Zehel et al. disclose an endoluminal apparatus for a variety of endoscopic procedures (see rejection above) but are silent with respect to a Y-port located along the first section, wherein the Y-port is in communication with at least one lumen extending through the elongated main body. Furihata teach of an analogous apparatus have a Y-Port 37 located proximally along the endoscope apparatus (see Fig. 3 and Col. 4, Lines 35-55). It would have been obvious to one skilled in the art at the time the invention was made to include a Y-port in the apparatus of Zehel et al. to enable a user to introduce additional surgical instruments at a desired site within the body as taught by Furihata.

Claims 92 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,251,611 to Zehel et al. in view of U.S. Patent No. 5,916,147 to Boury.

In regards to claims 92 and 94, Zehel et al. disclose an apparatus 1 comprising: a shaft 11 comprising a single tube having a first section, a second section

12 and a longitudinal axis; a plurality of first links 19 in the first section, with adjacent first links pivotably abutting each other but not connected to each other (see Fig. 3 and Col. 6, Lines 35-38), and with substantially each first link having a contoured front surface adapted to engage with a contoured back surface of an adjacent first link and having a plurality of first pullwire lumens 21; a plurality of first pullwires 20 extending through substantially each of the first pullwire lumens, with each of the first pullwires being fixed to the shaft at a location at or near a distal end of the first section and at substantially a common point along the longitudinal axis of the shaft, the first pullwires being substantially symmetrically spaced around the periphery of the first links of the first section (see Figs. 2 and 4 and Col. 6, Line 60 – Col. 7, Line 15); at least one second section steering wire (not shown) extending through substantially each of the first links and the second links (see Col. 4, Lines 34-36 and Col. 5, Lines 3-8); and at least one working lumen 29 extending through substantially each of the first links and the second links; and a scope extended through at least a portion of said at least one working lumen, said scope being moveable through said working lumen relative to said shaft (see Col. 6, Lines 14-16 and Col. 8, Lines 40-42). Zehel et al. teach that the distal end 12 may be optionally fitted with a wide variety of instruments for conducting a wide variety of exploratory, surgical or other procedures. For example, the device may be fitted with retractors to assist in retracting tissue away from the point of interest, ultrasonic devices, which for example, may be used in exploratory procedures, irrigation/suction devices for use in surgical procedures, tissue clipping devices, voice activated directional equipment, lock-on devices and the like (see Col. 5, Lines 48-65).

However, Zehel et al. are silent with respect to a plurality of second links in the second section, with adjacent second links pivotably abutting each other but not connected to each other, and with substantially each second link having a contoured front surface adapted to engage with a contoured back surface of an adjacent second link. Firstly, Zehel et al. teach of the desirability of providing such "non-connected" links within a guiding apparatus (see Figs. 2-4 and Col. 6, Line 40-60, Col. 8, Lines 1-36). Secondly, Boury teaches of an analogous endoscopic apparatus 10 comprising an elongated main body 30 having a proximal end 20, a distal end 16 and at least one lumen 142 extending through the main body the main body having at least a first section 36a near the proximal end and a second section 36d near the distal end, and with the first section comprising a plurality of nested links 140 with substantially all adjacent links having mating surfaces that are in contact with but that are not connected to each other (see Fig. 7 and Col. 13, Lines 43-67), wherein the first section may be selectively switched between a substantially flexible condition and a substantially rigid condition (see Col. 6, Lines 8-19) wherein the second section is steerable relative to the first section (see Fig. 2 and Col.7, Lines 47-56); and a scope being movable through the lumen relative to the elongated main body (see Col. 2, Lines 30-43). The proximal and distal segments are selectively moveable between an unlocked position wherein the locking segments are free to pivot with respect to one another and a locked position wherein the locking segments are constrained against relative movement. If so desired, the catheter can also include at least one control wire retained by the wall of the elongate tubular member, with the control wire extending proximally from the distal locking segment to a

location proximal of the proximal locking segment. This will permit one to remotely engage the locking segments in their locked position. Thus, it would have been obvious to one skilled in the art at the time the invention was made to provide a distal most section in the apparatus of Zehel et al. that is constructed of a plurality of links pivotally abutting each other to provide a selectively formable guide tube for an instrument, which allows a user to independently manipulate first and second sections of a guide tube as taught by Boury.

Response to Arguments

Applicant's arguments filed November 30, 2009 have been fully considered but they are not persuasive.

Applicant states that Zehel et al. fail to disclose a main body comprising a single tube. Examiner disagrees. As rejected above and as broadly as claimed, the single outer conduit 11 may be interpreted as being the main body of the apparatus, and thus the first section is simply the proximal portion of the tube (i.e. rigidizable links 19) and the second section is the flexible distal tip 12 (see Col. 5, Lines 48-65). Thus the outer conduit 11 meets the current limitation of a main body comprising a single tube. It is further noted that the transitional term "comprising", which is synonymous with "including," "containing," or characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.") (See MPEP 2111.03 Transitional Phrases). Thus, the claims stand rejected in view of Zehel et al.

Applicant's arguments with respect to claims 92 and 94 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Primary Examiner, Art Unit 3739

2/18/10